

Award Number:

W81XWH-10-1-0593

TITLE:

Probiotic (VSL#3) for Gulf War Illness.

PRINCIPAL INVESTIGATOR:

Ashok Tuteja, M.D. M.P.H.

CONTRACTING ORGANIZATION:

Western Institute for Biomedical Research
Salt Lake City, UT 84148

REPORT DATE: October 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

*Form Approved
OMB No. 0704-0188*

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.

1. REPORT DATE October 2016	2. REPORT TYPE Annual	3. DATES COVERED 8Sep2015 - 7Sep2016		
4. TITLE AND SUBTITLE Probiotic (VSL#3) for Gulf War Illness.			5a. CONTRACT NUMBER	
			5b. GRANT NUMBER W81XWH-10-1-0593	
			5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Ashok Tuteja, M.D. E-Mail: ashok.tuteja@va.gov			5d. PROJECT NUMBER	
			5e. TASK NUMBER	
			5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Western Institute For Biomedical Research Salt Lake City, UT 84148			8. PERFORMING ORGANIZATION REPORT NUMBER	
9 . SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)	
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited				
13. SUPPLEMENTARY NOTES				
14. ABSTRACT The overall objective of the study is to determine whether probiotic Visbiome™ will improve 1) Intestinal symptoms of Irritable Bowel Syndrome and 2) Non-intestinal symptoms (fatigue, joint pain, insomnia, general stiffness and headache) associated with IBS. All of these symptoms are part of the Gulf War illness. We screened our first participant in September 2013. Overall we have screened 73 and enrolled 34 Gulf War Veterans so far. Our efforts are ongoing to recruit more Gulf War veterans. The first set of stool samples have been sent to Lawrence Berkeley Laboratory for microbiota analysis.				
15. SUBJECT TERMS Irritable bowel syndrome, probiotic, Gulf War Illness, diarrhea				
16. SECURITY CLASSIFICATION OF: U		17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U		19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	1
Body.....	1
Key Research Accomplishments.....	2
Reportable Outcomes.....	3
Conclusion.....	4
References.....	5
Appendices.....	6

Introduction:

Gastroenteritis plays a major role in changing intestinal microflora. More than one third of Gulf War (GW) veterans report gastroenteritis during deployment and it is a risk factor for development of irritable bowel syndrome (IBS) after deployment. We also demonstrated that there is a strong association between IBS and extra-intestinal disorders (e.g. fatigue, joint pains, insomnia, generalized stiffness, and headache). This would suggest that IBS as well as extra-intestinal disorders in GW veterans have a unifying etiology. There is scientific evidence that probiotics by restoring normal gut flora improve symptoms of IBS. Probiotics have also been shown to improve arthritis and fatigue by changing fecal flora. This is the basis for our present protocol to study the effect of probiotics on GW illness.

Body:

The exclusive distributor of the probiotic in United States, will market and sell the probiotic VSL#3 under a different trade name Visbiome.TM We will be using VisbiomeTM as our study drug which has the same formulation as VSL#3

1. The University of Utah IRB and VA Research Office approved our amendment for change in the name of the Probiotic.
2. The FDA has no objection in the amendment for change in the name of the Probiotic.
3. The Department of Defense HRPO office approved our amendment for change in name of the probiotic.

During the last on year the following goals were accomplished:

- We have screened 72 GW veterans and enrolled 34 from the beginning of the study. Of the 34 veterans enrolled in the study, 28 have completed the study. Three veterans are on medication and nine veterans are in the screening phase. Two participants have been excluded from the study due to co-morbid conditions affecting the study assessment.
- The first set of stool samples have been sent to the Lawrence Berkeley laboratory for microbiota analysis.
- We have received the list of Gulf War Veterans in the Salt Lake City area from the Defense Manpower Database. We have send recruitment letters to these veterans informing them about the study.

Key Research Accomplishments.....

- We have recruited 34 Gulf War Veterans and continue to make progress in recruiting more Veterans.

Reportable Outcomes.....

Nil.

Conclusion:

Study is ongoing at a good pace as we planned. We continue our recruitment efforts to increase our study enrollment. First set of stool and blood samples will be analyzed.

References.....

Nil.

Appendices.....

Nil.

